U.S. DISTRICT COURT
DISTRICT OF VERMONT
FILED
2016 APR 29 PM 1:11
CLERK
BY DEPUTY CLERK

UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

JONATHAN A. BLOOM,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No.** 5:16-cv-121
	)	
SYLVIA BURWELL in her official capacity as Secretary, United States Department of Health and Human Services,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff, Jonathan A. Bloom, by his undersigned counsel, brings this action for judicial review of final agency decisions of Defendant Sylvia Burwell, in her official capacity as Secretary of the United States Department of Health and Human Services, and states as follows:

Preliminary Statement

1. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. §§1395 *et seq.* ("the Medicare Act"), and the Administrative Procedure Act ("APA"), 5 U.S.C. §§551 *et seq.* Plaintiff, Jonathan Bloom, seeks judicial review of a final decision of Defendant, the Secretary ("the Secretary") of the Department of Health and Human Services ("HHS"), denying Medicare payment for claims relating to a continuous glucose monitor.

2. Dr. Bloom has had Type I diabetes for over 40 years, which despite being consistently conscientious in following nutritional instructions, regularly exercising, performing frequent self-monitoring (six or more times daily), and following a comprehensive insulin administration regimen for his diabetes, his glucose levels still remain uncontrolled, i.e., "brittle."

3. Continuous glucose monitoring is the standard of care for individuals suffering from brittle diabetes.

4. Dr. Bloom was prescribed a continuous glucose monitoring device ("CGM") before he became eligible for Medicare.

5. Because CGM is the standard of care and is recognized as durable medical equipment, Dr. Bloom's commercial insurance company covered it for at least three years.

6. A National Coverage Determination ("NCD") is a determination by the Secretary regarding coverage that exists nationally. NCD 40.2 provides Medicare coverage for home blood glucose monitors for Medicare beneficiaries who suffer from diabetes.

7. In 2008, National Health Insurance Corporation ("NHIC") issued a local coverage determination ("LCD") L11530, indicating that blood glucose monitors and related accessories and supplies would be covered when (1) a patient had diabetes which was being treated by a physician; (2) the patient's physician states the patient is capable of using the device; and (3) the device is designed for home use rather than clinical use.

8. The NHIC LCD did not indicate that the CGM was not covered.

9. However, NHIC issued an informal communication known as an "Article" stating that NHIC considers CGM to be "precautionary."

10. The denials at issue in this action first arose when NHIC denied claims for Dr. Bloom's transmitter and sensors for his CGM on the basis they were convenience items.

11. Dr. Bloom appealed these denials through the multi-step Medicare Part B appeals process, ultimately filing appeals deemed timely with the Medicare Appeals Council ("AC").

12. The exhaustion of the Medicare appeals process took over a year and has resulted in inconsistent and unsupported decisions by the AC, which are the Secretary's final decisions for purposes of judicial review.

13. Plaintiff seeks an order reversing these coverage denials and instructing the Secretary to pay the claims at issue in accordance with applicable law. The decisions at issue are arbitrary and capricious, not supported by the evidence or Medicare law, regulation or guidance, and are inconsistent with the medical records and the medical standard of care.

Jurisdiction and Venue

14. The Court has subject matter jurisdiction under 42 U.S.C. §§405(g) and 1395ff(b) (appeal of final Medicare program agency decision) and under 28 U.S.C. §§1331 (federal question).

15. Venue lies in this judicial district under 42 U.S.C. §§405(g) and 1395ff(b) and 28 U.S.C. §1391(e).

16. Timely judicial review is being sought for a decision rendered by the Secretary. *See* 42 C.F.R. §405.1130 and §405.1134; ***see also*** **Exhibits 1 & 2.**

Parties

17. Jonathan Bloom is a Medicare beneficiary residing in South Burlington, Vermont, who is seeking Medicare coverage of his claims for CGM sensors and a transmitter.

18. Dr. Bloom has been a Medicare beneficiary since at least January 1, 2010.

19. Plaintiff brings this action, which is an appeal of the Secretary's final decisions denying Medicare claims for a CGM transmitter and sensors.

20. Defendant Sylvia Burwell is the Secretary of HHS, the federal department which contains the Centers for Medicare & Medicaid Services ("CMS"). The Secretary, the federal

official responsible for administering the Medicare Program, has delegated that responsibility to CMS.

Factual Background

A. General Background of the Medicare Program

21. The Medicare Act establishes a program of health insurance for the aged, disabled, and individuals afflicted with end-stage renal disease. *See* 42 U.S.C. §§1395 -1395ccc; 42 C.F.R. Parts 400 – 1004. Medicare includes Parts A through D. This action arises under Part B (covering basic non-hospital medical needs).

22. Under 42 U.S.C. §1395hh(a)(1), the Secretary is required to "prescribe such regulations as may be necessary to carry out the administration" of the Medicare program. That statute also states:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1). U.S.C. §1395hh(a)(2).

23. The Secretary has elected to publish many rules implementing the Medicare program in various manuals, such as the Medicare Program Integrity Manual ("MPIM") and the Medicare Claims Processing Manual ("MCPM"). However, under 42 U.S.C. §1395hh(a)(2), these manual provisions, which are not promulgated in accordance with the notice and comment provisions of the APA, are not effective to the extent that any of them "establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits" under Medicare.

B. Medicare Coverage and Payment of DMEPOS

24. Medicare Part B provides for coverage and payment for "medical and other health services," which includes durable medical equipment prosthetics, orthotics and supplies ("DMEPOS") provided to Medicare beneficiaries. *See* 42 U.S.C. §§1395k(a) and 1395x(n) and (s). To be paid by Medicare, medical devices and supplies must be found to be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *See* 42 U.S.C. §1395y(a).

25. Medicare adopts the FDA's determination of the safety and effectiveness of a medical device.

26. Durable medical equipment ("DME") is defined at 42 C.F.R. §414.202. DME (1) can withstand repeated use; (2) is primarily and customarily used to serve a medical purpose; (3) generally not useful to an individual in the absence of an illness or injury; and (4) appropriate for home use.

27. MCPM Ch. 15, § 110.1(B)(2) reiterates these requirements.

28. DMEPOS is categorized by CMS pursuant to the Healthcare Common Procedure Coding System ("HCPCS") and is assigned an alpha-numeric code consisting of a letter and a four-digit number. Some items of DMEPOS are assigned a unique HCPCS code. To obtain a unique code, a medical device or supply must achieve sufficient volume, *i.e.*, adoption within the medical community. *See* www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/decisiontree.pdf.

29. If Medicare covers a piece of DME, it also covers the supplies necessary for the effective use of the DME.

30. Claims for Medicare payment for DMEPOS items supplied to Medicare beneficiaries are presented to DME Medicare Administrative Contractors ("DMACs"). DMACs adjudicate

these claims as agents of the Secretary pursuant to contracts with her. The country is divided into four geographic jurisdictions, each of which has its own DMAC. A DMEPOS supplier must submit each of its claims to the DMAC having jurisdiction for reimbursement of that claim. *See* 42 C.F.R. §424.32.

31. After a claim has been submitted to the appropriate DMAC, the DMAC must determine if the item is covered or otherwise reimbursable under the Medicare Act. *See* 42 C.F.R. §405.920.

C. Medicare Coverage and Glucose Monitoring

32. A National Coverage Determination ("NCD") is "a determination by the Secretary of whether a particular item or service is covered nationally under Medicare." *See* 42 C.F.R. §405.1060(a)(1).

33. An NCD is binding on all Medicare contractors, including administrative law judges ("ALJs") and the AC. *See* 42 C.F.R. §405.1060(a)(4).

34. NCD 280.1, Durable Medical Equipment Reference List, reflects the Secretary's determination of items that she deems to be DME. NCD 280.1 includes blood glucose monitors.

35. To further ensure coverage of diabetic testing equipment and supplies, in 2006, the Secretary issued the current effective version of an additional NCD providing Medicare coverage for blood glucose monitors. *See* Medicare National Coverage Determinations Manual §40.2, Home Blood Glucose Monitors (hereinafter "NCD 40.2").

36. Under NCD 40.2, a home blood glucose monitor, and therefore related supplies, is covered when:

a. The patient has been diagnosed as having diabetes;

b. The patient's physician states that that the patient is capable of being trained to use the particular device prescribed in an appropriate manner; and

c. The device is designed for home rather than clinical use. *Id.*

37. Neither NCD 280.1 nor 40.2 distinguishes between single use glucose monitors or continuous use glucose monitors.

38. In addition to an NCD, MACs, including DMACs, can issue local coverage determinations ("LCDs").

39. LCDs are issued after consideration of the peer-reviewed literature, consultation with the relevant medical community, notice and comment. *See* Medicare Program Integrity Manual ("MPIM") Ch. 13, §13.7.

40. When the ALJ is rendering a decision, although not bound by an LCD, an ALJ must give deference to an LCD. *See* 42 C.F.R. §405.1062. If an ALJ does not give deference to an LCD, the ALJ must explain why he or she did not.

41. In 2008, National Government Services ("NHIC") issued LCD L11530 indicating that blood glucose monitors and related accessories and supplies would be covered when (1) a patient had diabetes which was being treated by a physician; (2) the patient's physician states the patient is capable of using the device; and (3) the device is designed for home use rather than clinical use.

42. The NHIC LCD did not and does not indicate that a CGM and related accessories and supplies were not and are not a Medicare covered benefit. The NHIC LCD includes the HCPCS codes associated with a CGM and its supplies.

43. Articles are informal communications issued by MACs and may be issued without consultation with the relevant medical community or the peer reviewed literature. Articles are

not subject to challenge by providers or beneficiaries, and are not entitled to any deference by either the QIC or ALJ. *See* 42 C.F.R. §405.1062.

44. Articles are not binding on ALJs, the AC, or other Medicare contractors. *See, e.g., In the Case of The Rehabilitation Center, Inc.*, ALJ Appeal No. 1-801426411, M-2012-328 (Medicare Appeals Council, Feb. 24, 2012).

45. Congress has made clear that enabling Medicare beneficiaries suffering from diabetes to manage and control their condition can reduce the complications from the disease and costs (*e.g.,* hospital and emergency room visits) to the Medicare program.

46. The Secretary has made numerous public pronouncements and engaged in various initiatives exhorting Medicare beneficiaries to control their diabetes to prevent diabetic complications and the attendant costs to the Medicare program.

D. The Process for Appeals of Medicare Claims Decisions

47. Congress has established a five-step process for a Medicare beneficiary, such as Dr. Bloom, to follow to obtain judicial review when he is dissatisfied with the initial determination of a claim by the DMAC.

48. The first step in the process is request for redetermination by the DMAC. *See* 42 C.F.R. §§405.940 through 405.958.

49. Upon a request for redetermination, the DMAC is required to adjudicate a claim and render a decision based on the evidence in the record. *See* 42 C.F.R. §405.954. Under 42 C.F.R. §405.956(b), the redetermination notice issued by the DMAC must include, *inter alia*, a summary of the evidence used in making the redetermination; an explanation of relevant laws, regulations, coverage rules, CMS policies that apply to the case; and a summary of the rationale for the redetermination in clear, understandable language. *See* 42 C.F.R. §405.956(b).

50. A Medicare beneficiary who is dissatisfied with a DMAC's redetermination decision may request reconsideration by the DME qualified independent contractor ("QIC"). *See* 42 C.F.R. §405.960. The QIC is required to review the record of the claims and issue a reconsideration decision having the same decision elements as the DMAC's redetermination decision. *See* 42 C.F.R. §405.976(b).

51. A Medicare beneficiary may appeal the QIC reconsideration decision by requesting a hearing before an Administrative Law Judge ("ALJ"). *See* 42 C.F.R. §405.1000.

52. ALJs are bound to follow an NCD. *See* 42 C.F.R. §405.1060(a)(4).

53. In contrast to an NCD, local coverage determinations ("LCDs") issued by MACs, including DMACs, are not binding on an ALJ. *See* 42 C.F.R. §405.1062(a).

54. When the ALJ is rendering a decision, although not bound by an LCD, if an ALJ applies an LCD, the ALJ must apply the LCD in place on the date the item or service was provided. *See* 42 C.F.R. §405.1034.

55. Articles, which are informal communications issued by MACs, may be issued without consultation with the relevant medical community. Articles are not subject to challenge by providers or beneficiaries, and are not entitled to any deference by either the QIC or ALJ. *See* 42 C.F.R. §405.1062.

56. Pursuant to the statute and Medicare regulations, an ALJ should render a decision within 90 days of a request for an ALJ hearing. 42 U.S.C. §1395ff(d)(1)(a); 42 .C.F.R §405.1016(a).

57. If an ALJ issues an unfavorable decision, a Medicare beneficiary may appeal the decision to the AC.

58. If an ALJ issues a favorable decision, the AC may review the case by its own motion, a process frequently initiated by an appeal of a favorable decision by CMS or any of its contractors through a referral of the case to the AC. *See* 42 C.F.R. §405.1110(a); 42 C.F.R. §405.1110(b).

59. An NCD is binding on the AC and the AC limits its review to the evidence contained in the record before the ALJ. *See* 42 C.F.R §405.1122(a)(1).

60. Pursuant to the statute and Medicare regulations, the AC should render a decision within 90 days of a request for AC review. *See* 42 U.S.C. §1395(d)(2)(a); 42 C.F.R. §405.1100(c).

61. The AC's decision becomes the Secretary's decision and is the final agency decision for purposes of judicial review. *See* 42 C.F.R. §405.1136(d).

62. A Medicare beneficiary seeking judicial review of the Secretary's final decision may file a complaint "in the district court of the United States for the judicial district in which the party resides or where such individual, institution, or agency has its principal place of business." *See* 42 C.F.R. §405.1136; *see also* 42 U.S.C. §§405(g) and 1395ff(b).

E. The Process for Challenging an LCD

63. Medicare regulations also provide a mechanism for a Medicare beneficiary to file a challenge against an LCD. *See* 42 C.F.R. §426.400 et seq.

64. The LCD challenge process is independent from the claims appeal process and is conducted by an ALJ who is a member of the Civil Remedies Division of the Departmental Appeals Board of the Department of Health and Human Services (the "Board"). *See* 42 C.F.R. §426.310.

65. When a Medicare beneficiary files an LCD challenge, the relevant MAC is required to produce any information that the MAC considered when drafting an LCD, including scientific articles, technology assessments, clinical guideless and statements from clinical experts (the "LCD Record"). *See* 42 C.F.R. §426.418.

66. The ALJ reviews the evidence submitted by the MAC and applying the reasonableness standard, determines whether the LCD Record is complete and adequate to support the validity of the LCD. *See* 42 C.F.R. §426.425(c).

67. If the ALJ determines the LCD is not valid under the reasonableness standards, the MAC must provide individual consideration for the claim that gave rise to the LCD challenge, and all subsequent claims for the same device or service, without using the LCD or LCD provisions found to be invalid. *See* 42 C.F.R. 426.460(b)(1).

Statement of Facts and Prior Proceedings

A. Continuous Glucose Monitoring and Brittle Diabetes

68. Unfortunately, despite consistently and conscientiously following nutritional instructions, regularly exercising, performing frequent self-monitoring (six or more times daily), and following a comprehensive insulin administration regimen for their diabetes, some individuals still have uncontrolled glucose levels. Such individuals suffer from "brittle diabetes."

69. Such individuals suffer from hypoglycemic unawareness, *i.e.,* they are unaware of an impending, dangerous low drop in blood glucose. Hypoglycemic unawareness may result in prolonged and profound exposure to hypoglycemia, resulting in seizure, loss of consciousness and brain damage.

70. Individuals suffering from brittle diabetes often have frequent nighttime hypoglycemic episodes which causes a progressive loss of mental function and death.

71. Approximately one in 20 apparently healthy individuals suffering from type one diabetes will die in their sleep from an unknown cause which is widely believed to be associated with a hypoglycemic low. This is known as "dead in bed syndrome."

72. CGM alerts a person suffering from brittle diabetes of both hypo- and hyperglycemic episodes, which can occur at a frequency that would confound any attempt to manage through simple finger-stick blood glucose checks.

73. CGM operates by measuring the interstitial fluid under the skin which, as the device name implies, continuously tracks with and reflects the glucose concentration in the blood.

74. CGM is a physician-prescribed, FDA-approved medical device.

75. CGM is used solely by individuals with diabetes to aid in the treatment of their disease.

76. CGM has been recognized as the standard of care for individuals suffering from brittle diabetes nationally and internationally.

77. Medical consensus statements/guidelines reflecting CGM as the standard of care for brittle diabetics have been issued by the American Association of Clinical Endocrinologists Consensus Panel on Continuous Glucose Monitoring (which has recommended CGM since at least 2007); the American Diabetes Association (which has included the CGM in its recommendation since at least 2009); the Endocrine Society; the German Diabetes Association (which reviews the favorable consensus statements of many European nations); various French Endocrinology and Diabetic Societies; the European Society for Pediatric Endocrinology, the Pediatric Endocrine Society and the International Society for Pediatric and Adolescent Diabetes.

78. The American Medical Association passed a resolution in support of CGM coverage for Medicare beneficiaries.

79. The consensus of medical opinion regarding the safety and effectiveness of CGM for individuals suffering from brittle diabetes is supported by at least nine peer-reviewed publications reflecting randomized, controlled clinical trials.

80. Based on the consensus statements, peer-reviewed literature and widespread acceptance of CGM for brittle diabetics, more than 95% of commercial insurers cover CGM.

81. An independent federally-funded technology assessment found CGM reasonable and medically necessary for individuals suffering from brittle diabetes. *See* the Agency for Health Care Research and Quality ("AHRQ") report of 2010 (AHRQ at 102-103, 105).

B. The Proceedings Below Relating to the Claims at Issue in this Action

82. This is an action for judicial review of the final administrative decision of the Secretary with ALJ Appeal 1-2911738005 and 1-2838936764, AC M-15-4332 (issued February 24, 2016); and ALJ Appeal 1-3178475308, AC M-15-1505 (issued November 13, 2015). ***See* Exhibits 1 & 2.**

83. Dr. Bloom has had Type 1 diabetes for over 40 years.

84. Despite frequent testing, he was unable to gain control of his diabetes. He also suffers from hypoglycemia and hypoglycemic unawareness.

85. Accordingly, his healthcare provider prescribed him a continuous glucose monitor, which checks Dr. Bloom's glucose approximately 288 times a day and alerts him when he is experiencing a hypoglycemic event.

86. Dr. Bloom's healthcare provider attested that CGM was and is reasonable and medically necessary for Dr. Bloom to control his diabetes.

87. With CGM, Dr. Bloom had a vast clinical improvement of his blood glucose level control.

88. Dr. Bloom filed claims for the related sensors and a transmitter for his CGM which were denied by NHIC on the basis they were convenience items.

89. Before the decisions at issue, Dr. Bloom had received multiple favorable determinations from multiple ALJs finding CGM to be reasonable and necessary for Dr. Bloom. *See* ALJ Appeal 1-801593711; ALJ Appeal 1-946049364; ALJ Appeal 1-1779943353; ALJ Appeal 1-2381371020. ***See* Exhibits 3-6.**

90. With respect to the claims at issue in this case, Dr. Bloom appealed the denials through the Medicare administrative appeal process.

91. Dr. Bloom filed timely requests for an ALJ hearing.

92. ALJ hearings were conducted on March 31, 2015 before Judge Jarboe (ALJ Appeal 1-2838936764); March 31, 2015 before Judge Dorman (ALJ Appeal No. 1-2911738005); and June 16, 2015 before Judge Engelman (ALJ Appeal No. 1-3178475308).

93. Dr. Bloom submitted letters from his healthcare providers attesting to the fact that CGM was not precautionary but was medically necessary and essential for Dr. Bloom.

94. The providers explained that Dr. Bloom's medical need for CGM is extreme.

95. Dr. Pratley noted that CGM is essential for Dr. Bloom given persistent and frequent hypoglycemic episodes (April 29, 2009 letter).

96. Although Medicare ALJs may retain a clinical and scientific expert to facilitate their understanding of the case, the ALJs did not retain such an expert in these cases.

97. ALJ Engelman issued a favorable ALJ decision (ALJ Appeal No. 1-3178475308), and the other ALJs issued unfavorable decisions. ***See* Exhibit 7.**

98. Dr. Bloom appealed the unfavorable ALJ decisions to the AC.

99. On August 21, 2015, the Medicare Administrative Qualified Independent Contractor ("AdQIC"), Q2 Administrators, LLC filed a Referral on ALJ Appeal No. 1-3178475308, requesting that the AC review the ALJ Engelman's favorable decision.

100. While Dr. Bloom was pursuing his claims through the Medicare claims appeal process, on December 2014, an unrelated Medicare beneficiary filed a challenge to the provision in the NHIC Article that asserted CGM was precautionary.

101. NHIC was required to produce all information upon which NHIC determined CGM was precautionary. NHIC did not produce a single peer-reviewed publication or proffer the testimony of a single medical professional expert in support of its assertion that CGM was precautionary. In fact, NHIC submitted no evidence for consideration.

102. On September 11, 2015, Judge Sickendick of the DAB Civil Remedies Division found that under a reasonableness analysis, the Article provision asserting that CGM was precautionary was not supported by the LCD Record. *See* CRD Docket No. C-15-1021.

103. Judge Sickendick also found that CGM met the statutory definition of DME.

104. On February 24, 2016, the AC affirmed the ALJ's denial of Medicare coverage of the CGM transmitter and sensors in the consolidated case of M-15-4332 (ALJ Appeal Nos. 1-2911738005 & ALJ Appeal No. 1-2838936764) (the "4332 Decision"). On November 13, 2015, the AC reversed the ALJ's approval of the CGM sensors at issue in ALJ Appeal No. 1-3178475308, M-15-1505 (the "1505 Decision") (collectively, the "Decisions"). ***See* Exhibits 1 & 2.**

105. Without support, and ignoring Judge Sickendick's explicit findings, the AC found that the CGM is simply precautionary, does not serve a medical purpose, and therefore the CGM transmitter and sensors are not covered under the DME Medicare benefit.

106. The Secretary stated that because CGM does not substitute for fingersticks and does not directly measure blood glucose, CGM "merely provides an added precaution" and does not "serve a primary medical purpose."

107. The Secretary compared CGM to "spare tanks" of oxygen.

108. The Secretary's Decisions are contrary to the overwhelming medical and scientific evidence; and are contrary to her own determinations in regarding the evidence supporting CGM.

Count I
Arbitrary and Capricious and Unsupported by Substantial Evidence Under the APA (CGM is Medically Necessary Medical Equipment for Type 1 Diabetes)

109. Plaintiff hereby incorporates by reference paragraphs 1 to 108 herein.

110. Under the Medicare statute, 42 U.S.C. §1395ff(b), the final agency decision included in this action is subject to judicial review. Under the APA, the reviewing court shall set aside the final agency decision if, *inter alia,* it is contrary to law, arbitrary and capricious, an abuse of discretion, or unsupported by substantial evidence in the record.

111. To the extent that the Secretary's Decisions in this action found that CGM and its related supplies are precautionary and do not serve a medical purpose and therefore not reasonable and medically necessary, the Secretary's decisions must be set aside because they are contrary to law, arbitrary, capricious, and unsupported by substantial evidence in the record.

112. Further, to the extent that the Secretary's Decisions in this action found that CGM and its related supplies are not durable medical equipment and therefore not reasonable and

medically necessary, the Secretary's decisions must be set aside because they are contrary to law, arbitrary, capricious, and unsupported by substantial evidence in the record.

113. CGM is recognized nationally and internationally by clinicians, researchers, and payers, as a reasonable and medically necessary medical device which has become the standard of care for individual suffering from Type 1 diabetes with hypoglycemic unawareness.

114. The FDA approved CGM as a safe and effective medical device and it is prescribed by a physician.

115. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decisions and issue an order finding that the CGM is not precautionary and is reasonable and medically necessary for Dr. Bloom, and direct the Secretary to make appropriate payment for the transmitter and sensors for the device that are the subject of this case.

Count II
Arbitrary and Capricious and Unsupported by Substantial Evidence Under the APA
(The Decisions Are Contrary to the Secretary's Other Determinations)

116. Plaintiff hereby incorporates by reference paragraphs 1 to 115 herein.

117. Under the Medicare statute, 42 U.S.C. §1395ff(b), the final agency decisions included in this action is subject to judicial review. Under the APA, the reviewing court shall set aside the final agency decision if, *inter alia,* it is contrary to law, arbitrary and capricious, an abuse of discretion, or unsupported by substantial evidence in the record.

118. To the extent that the Secretary's Decisions in this action found that CGM and its related supplies are precautionary and therefore not covered under the Medicare durable medical benefit, the Secretary's Decisions must be set aside because they are contrary to law and arbitrary and capricious, an abuse of discretion and not supported by substantial evidence.

119. The Secretary repeatedly has determined CGM is durable medical equipment covered under the Medicare DME benefit and is reasonable and medically necessary for Medicare beneficiaries suffering from Type 1 diabetes with hypoglycemic unawareness.

120. The Secretary repeatedly has determined CGM is DME and is reasonable and medically necessary for Dr. Bloom based on the same information which she now deems not to support Medicare coverage of CGM for Dr. Bloom.

121. Based on the foregoing, the Secretary's Decisions are contrary to Medicare regulations, arbitrary and capricious, and unsupported by substantial evidence in the record, and Plaintiff asks the Court to reverse the Secretary's Decisions and issue an order finding that the CGM is reasonable and medically necessary for Dr. Bloom, and direct the Secretary to make appropriate payment for the transmitter and sensors for the device that are the subject of this case.

Count III
Violation of APA as Contrary to Law
(The Decisions Are Contrary to the Act, NCDs, the LCD and Regulations)

122. Plaintiff hereby incorporates by reference paragraphs 1 to 121 herein.

123. The Secretary's Decisions in this action must be set aside because they are contrary to law, arbitrary, capricious, and unsupported by substantial evidence in the record.

124. The Secretary's findings that CGM is precautionary and not primarily medical, not DME and not covered by Medicare, are contrary to Section 1861(n) of the Act and the Secretary's determinations reflected in NCDs 280.1 and 40.2 which provide national coverage for glucose monitors.

125. Further, the Secretary's Decisions are contrary to the LCD, which provides coverage criteria for glucose monitors and which Mr. Bloom satisfied.

126. Further, to the extent the Secretary deems CGM not to be DME, that finding is inconsistent with the regulatory DME definition cited in her Decisions.

127. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decisions as contrary to law, as arbitrary, capricious and unsupported by the evidence, and issue an order finding that the CGM and its related supplies are eligible for coverage under the Act, NCD 280.1, NCD 40.2, and Medicare regulations, and reasonable and medically necessary for Dr. Bloom.

Count IV
Contrary to Law Under the APA
(Improper Deference to an Article)

128. Plaintiff hereby incorporates by reference paragraphs 1 to 127 herein.

129. To the extent that the Secretary's Decisions are premised on giving deference to an NHIC Article, which is not an LCD and is not entitled to deference, the Secretary's Decisions must be set aside because they are contrary to law, regulation and arbitrary and capricious, and not supported by substantial evidence.

130. The Secretary provided no basis for giving deference to an Article, declining to follow her NCDs, the relevant LCD, or acknowledging that even if the Article applied, it should not be given deference in view of Dr. Bloom's uncontested dire need for CGM to avoid life-endangering glucose swings.

131. The Secretary provided no basis for applying the Article which has been found not supported by clinical and scientific evidence.

132. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decisions and issue an order finding that the Secretary's deference to an Article was contrary to law, arbitrary and capricious and unsupported by substantial evidence, and that CGM and its

related supplies are reasonable and medically necessary for Dr. Bloom, and order the Secretary to make payment on the claims at issue and any future claims for Dr. Bloom's CGM and supplies.

Requested Relief

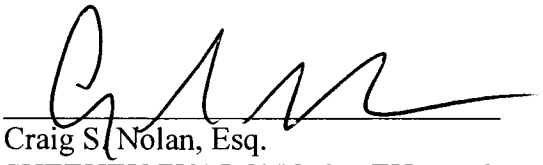
WHEREFORE, Plaintiff requests:

1. An order setting aside the Secretary's Decisions that the CGM, and therefore its transmitter and sensors, are precautionary and not primarily medical, and therefore not covered by Medicare;
2. An order declaring CGM and its related supplies are eligible for Medicare coverage under the DMEPOS benefit;
3. An order remanding this action to the Secretary with instruction to cover Dr. Bloom's CGM transmitter and sensors as reasonable and medically necessary and any future claims for CGM and its supplies;
4. An order that this Court will retain jurisdiction over the decisions at issue until the Secretary's payment of the claims at issue has been completed;
5. An order awarding legal fees and costs of suit incurred by Plaintiff; and
6. Such other relief as this Court may deem and consider appropriate.

Dated at Burlington, Vermont this 29th day of April, 2016.

Respectfully submitted,

JONATHAN A. BLOOM

By: 

Craig S. Nolan, Esq.
SHEEHEY FURLONG & BEHM P.C.
30 Main Street
P.O. Box 66
Burlington, Vermont 05402-0066
(802) 864-9891
cnolan@sheeheyvt.com

Debra M. Parrish, Esq. (*pro hac vice papers to be filed*)
Bridget M. Noonan, Esq. (*pro hac vice papers to be filed*)
PARRISH LAW OFFICES
788 Washington Road
Pittsburgh, PA 15228
(412) 561-6250
debbie@dparrishlaw.com
bridget@dparrishlaw.com

Attorneys for Plaintiff